

REMARKS

Claims 1-14, 16-28, 31, 33-42 and 45-46 are presently pending in this application. Claims 15, 29, 30, 32, 43, 44 and 47-49 have been canceled without prejudice. Claims 1, 4-10, 14, 16, 19-24, 26-28, 33-38, 45 and 46 have been amended as discussed below. Additionally, for the reasons described below, no new matter has been added by these amendments.

At the outset, applicants acknowledge the withdrawal of all outstanding rejections, including the § 103 rejections.

35 U.S.C. § 112, ¶ 1

Claims 26-30, 33, 34 and 47-49 were rejected under 35 U.S.C. 112, ¶ 1 for alleged lack of enablement. Specifically the Examiner asserts that “[t]here is no evidence of record which would enable the skilled artisan in the identification of the people who have the potential of becoming afflicted with the numerous diseases/disorders or the various methods by which detection of the diseases/disorders as claimed herein.”

Applicants respectfully disagree and assert that the claims are fully enabled. However, in order to expedite prosecution applicants have amended the claims to obviate these rejections. Specifically, claim 26 has been amended, *inter alia*, to remove the recitation “detecting the presence or assessing the severity of an oncological, neurological, inflammatory, infectious and degenerative disease, disorder or abnormal physical state” and claims 29-30 have been canceled. Claim 33 has been amended similarly to claim 29 and claims 47-49 have been canceled. Applicants note that the remaining claims, 27 and 28, depend from claim 26 and are thus enabled for the same reason as independent claim 26.

35 U.S.C. § 112, ¶ 2

Claims 1-14, 16-31, 33-42 and 45-49 were rejected under 35 U.S.C. 112, ¶ 2 as allegedly indefinite.

Applicants note the Examiner's suggestions regarding the wording of the claims. Applicants believe the claims previously submitted are in full compliance with § 112. Each of the Examiner's suggestions regarding the claims is addressed separately below. Applicants state that to the extent they have accepted the Examiner's proposed amendments, it is solely to expedite prosecution and is not for any reason related to patentability, as the claims as written are definite.

Claim 1: The Examiner has suggested that the claim be amended to require a complex-forming metal ion. Applicants disagree. The instant claim is directed to a composition useful for generating a labeled agent, not to the final labeled agent composition per se. Thus, it is essentially an intermediate and as such a complex-forming metal agent is not required. It is only necessary that, as stated in the claim, in the presence of a complex-forming metal ion, the conjugate coordinates with the complex-forming metal and is released from the support surface. Comparison with claim 19 illustrates this point. However, applicants have amended claim 1 to require a "A composition for generating a complex-forming metal ion labeled conjugate, the composition comprising...." This language clarifies that the conjugate is being labeled.

Claim 4: The Examiner has requested that the claim be amended to replace conjugate with targeting molecule. Thus, it would require that the targeting molecule comprise a peptide, polypeptide, peptide or polypeptide mimetic or an organic molecule having a mw of less than about 600. Applicants have hereinabove amended claim 4 to replace "conjugate" with "targeting molecule."

Claim 5: The Examiner has requested that the claim be amended to replace conjugate with targeting molecule. Thus, it would require that the targeting molecule comprise a peptide sequence selected from a recited list. Applicants have hereinabove amended claim 5 to replace “conjugate” with “targeting molecule.”

Claim 6: The Examiner suggests deleting this claim, which requires that the conjugate comprises a small organic molecule that targets a receptor or transporter. Instead, Applicants have amended this claim to replace conjugate with targeting molecule. Support for this amendment can be found on page 11 of the specification which states “The targeting molecule preferably includes a...small organic molecule that targets a receptor or transporter. The receptor or transporter is preferably a dopamine receptor or transporter, a serotonin receptor or transporter, a sigma receptor, a GABA receptor, a nicotinic receptor, a cholinergic receptor, a norepinephrine receptor or transporter, a glucose transporter and an opioid receptor.”

Claim 7: The Examiner has suggested that “the limitations of claim 10 should be incorporated in to claim 10”. Applicants assume that the Examiner meant to refer to claim 7 at the end of the sentence and thus that the Examiner is requesting a similar amendment to that proposed for claim 38. Thus, Applicants have amended claim 7 accordingly.

Claim 8: The Examiner has suggested that claim 8 be amended to replace ligand with targeting molecule. As with claim 4, although the current claim language is fully supported, applicants have hereinabove amended claim 8 to recite “targeting molecule” instead of “ligand.”

Claim 9: The Examiner has suggested that N_xS_{4-x} be deleted. In lieu of the Examiner’s suggestion, applicants have hereinabove amended this claim to clarify that the ligand comprises a peptide selected from the group consisting of a tetradentate N_3S ligand, and a polyamino polysulfide. Support for this amendment can be found at page 10 of the specification

which reads: “[p]referred ligands of the invention include molecules incorporating a sulfur surface binding atom and at least 3 nitrogen atoms....”

Claim 10: The Examiner has suggested deleting this claim. However, applicants believe it further defines the targeting molecule, and thus for the same reasons as claim 8, from which it depends, applicants believe that claim 10 is not indefinite.

Claim 14: The Examiner has suggested deleting the dependency from claim 6. As amended, claim 14 now depends from claim 5.

Claim 16: The Examiner would like to replace “comprises” with “is”. Although applicants believe that the claim is fully compliant with section 112, solely to expedite prosecution and not for any reason related to patentability, applicants have amended claim 16 as suggested.

Claim 19: The Examiner would like to rewrite the claim to state: “A method of generating a complex-forming metal ion labeled diagnostic agent or radiotherapeutic agent comprising contacting the composition of claim 1 with a metal ion to form a coordinate bond between the metal ion and conjugate so that the labeled conjugate is released from the support.” This proposed amendment is largely acceptable in principle to the applicants. However, applicants would like to clarify that the labeled conjugate is used as the diagnostic or radiotherapeutic agent; and thus have amended the claim language as follows:

A method of generating a complex-forming metal ion
labeled conjugate for use as a diagnostic or radiotherapeutic
agent comprising....

Claim 20: The Examiner has proposed re-writing the claim as follows: “The method of claim 19 further comprising collecting the labeled conjugate released.” Although applicants believe that the claim is fully compliant with section 112, solely to expedite

prosecution and not for any reason related to patentability, applicants have amended claim 20 as suggested.

Claim 21: The Examiner proposes deleting this claim. Applicants have amended this claim to recite a metal ion labeled conjugate prepared using a composition of claim 1. As explained above, claim 1 is not duplicative as it does not require a metal ion labeled agent, but rather is directed to a composition useful in labeling. Thus applicants respectfully assert that claim 21 is not indefinite.

Claim 22: The Examiner has proposed re-writing this claim. However, applicants respectfully disagree with the Examiner's proposed language. The claim proposed by the Examiner is directed to a method of preparing a labeled agent. However, claim 22 is directed to a labeled conjugate with recited properties. Therefore, applicants have amended the claim to read as follows:

A technetium or rhenium labeled conjugate prepared using a composition of claim 1, wherein the conjugate is labeled with ^{99m}Tc and has a specific activity of greater than 10,000 Ci/mmol or with ^{188}Re and has a specific activity of greater than 3,000 Ci/mmol.

Thus, applicants respectfully assert that claim 22 is not indefinite.

Claim 23: Applicants respectfully disagree with the Examiner's proposed amendment to claim 23, which depends from claim 22, for the same reasons as with claim 22 above (*i.e.* claim 23 is also directed to a composition having certain properties). However, to speed prosecution applicants instead propose, and have so amended claim 23 to read as follows:

The composition of claim 22, wherein the conjugate comprises a peptide, diethylglycylserinylcysteinylglycine.

Therefore, applicants respectfully assert that claim 23 is not indefinite.

Claim 24: Applicants respectfully disagree with the Examiner's suggested amendment because it does not include a complex-forming metal ion. Instead, applicants propose, and have amended, the claim to depend from claim 21 (which recites a metal ion labeled conjugate prepared using a composition of claim 1). As amended, claim 24 reads as follows:

A pharmaceutical composition comprising a
pharmaceutically acceptable carrier and the metal ion
labeled conjugate of claim 21.

Thus, applicants respectfully assert that claim 24 is not indefinite.

Claim 26: The Examiner has proposed re-writing the claim as a method of imaging dependent on claim 24. In light of applicants' amendment to claim 24 to require a metal ion labeled conjugate, applicants accept this suggestion.

Thus, applicants respectfully assert that claim 26 is not indefinite.

Claim 27: The Examiner has proposed re-writing the claim as a method of radiotherapy. This is acceptable to applicants in principle. However, the claim cannot depend from claim 1 as the Examiner suggests because claim 1 does not require a metal ion. Thus Applicants suggest that the claim depend from claim 24 as follows:

A method of radiotherapy in a mammal comprising
administering an effective amount of the composition of
claim 24.

Thus, applicants respectfully assert that claim 27 is not indefinite.

Claim 28: The Examiner's proposed amendment is acceptable.

Claims 29 and 30: Solely to expedite prosecution and not for any reason related to patentability, applicants have canceled these claims without prejudice. Therefore the § 112 ¶2 rejection is rendered moot.

Claim 33-46: Solely to expedite prosecution and not for any reason related to patentability applicants have amended claims 33-46 as suggested by the Examiner.

Claims 47-49: The Examiner has proposed deleting these claims as redundant. To expedite prosecution, applicants agree to cancel claims 47-49 without prejudice, subject to their being reasserted in the event claims 26, 27 and 33 are not deemed allowable.

Applicants respectfully assert that any § 112 ¶ 2 rejections are now rendered moot by the applicants' adoption of the Examiner's suggested amendments or by the amendments made by the applicants as described above.

In light of the present amendments and remarks, Applicants respectfully submit that the presently pending claims are in condition for allowance, early notice of which is earnestly sought. If any outstanding issues remain, the Examiner is invited to telephone Applicants' representatives to discuss the same.

No fees are believed to be required for the filing of this *Amendment and Response to Office Action*. However, please charge any additional required fees, and credit any overpayments, to Deposit Account No. 50-0540.

Respectfully submitted,

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